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08/903,677 07/31/97 HANSON

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EXAMINER

QM12/0909

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| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 09/09/99

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 15

Application Number: 08/903,677

Filing Date: July 31, 1997

Appellant(s): HANSON, Carl E.

Karl G. Hanson
For Appellant

EXAMINER'S ANSWER

2000-08-20

This is in response to appellant's brief on appeal filed August 20, 1999.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

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A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 1-17 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *ClaimsAppealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

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Singh, R. B. Et al. "Usefulness of Antioxidant Vitamins in Suspected Acute Myocardial Infarction (The Indian Experiment of Infarct Survival-3)." The American Journal of Cardiology, vol. 77, no. 4 (February 1, 1996), pp. 232-6.

Langtry, H. Et al. "Nisoldipine Coat-Core: A Review of its Pharmacodynamic and Pharmacokinetic Properties and Clinical Efficacy in the Management of Ischemic Heart Disease." Drugs, vol. 53, no. 5 (May, 1997), pp. 867-884.

Riemersma, R. A. Et al. "Risk of angina pectoris and plasma concentrations of vitamins A, C, and E and carotene." The Lancet, vol. 337, no. 8732 (January 5, 1991), pp. 1-5.

Dapcich-Miura, E. "Contingent Management of Adherence to a Complex Medical Regimen in an Elderly Heart Patient." Behavior Therapy, Vol. 10, no. 2 (1979), pp. 193-201.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As to the specification, Applicant has given no proof that the method as claimed would prevent "chest pain". Even though Applicant may attest that Applicant has received "beneficial

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effects" from drinking a large quantity of lime juice, this is not evidence in a scientific qualitative sense that ingesting a large quantity of lime juice or vitamin C would prevent any medically defined ailments. As noted in the top of page 1 of the specification, "symptoms [of chest pains] are most often induced by some physical or emotional stress ...". Any psychological effects from drinking lime juice, without physical proof of relief from ailments, will not be considered to be operative in a medically accepted and patentable method of treating a disease or the like. In fact, it is well known that "placebo effects" are common in individuals who believe that certain "medication" have alleviated their medical ailments, while in reality such "medication" were inactive and while in reality, placebos given to them instead. Applicant's condition as described in the specification, may be due to the wide belief that vitamin C, and related sources such as orange juice, are good for the body. In fact, it has been shown that excessive vitamin C may damage the body to a certain extent.

Lastly, Applicant has not shown proof of what is considered the "active ingredients" as briefly discussed at the bottom of page 3 of Applicant's specification, or the "effective amount" as claimed in the claim language. Absent a showing of scientifically and reliable proof that the claimed method works as to the treatment of "chest pains", the present disclosure by Applicant is considered non-operative and non-enablement.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention. See the above paragraphs for details. Additionally, the following applies to individual claims.

As to claim 1, at line 4, it is not clear what “effective amount” consists of for the treatment as claimed.

As to claims 15 and 16, it is not clear what the “active ingredients” are for the treatment as claimed.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Singh et al., Langtry et al., Riemersma et al., or Dapcich-Miura et al. Applicant has merely claimed a method of treating “chest pain” by taking lime juice. The above references all disclose a method of treating angina (medical terminology for a particular type of “chest pain”) or related “chest pain” by taking vitamins, i.e., vitamin C, or fruit juices. Since Applicant has not shown the particular advantages over taking lime juice over other juices which contain vitamin C, and related vitamins and chemical composition, the use of lime juice is equated with the use of other citrus juices. Further, Applicant has not shown what is considered the “effective” substance and “effective” dosages of the juice in treating chest pain, the differences in dosage is treated as a “design choice” similar in the way a person increase or decrease medical dosages depending on the severity of the medical condition. Therefore, although the above cited references do not disclose the exact dosage of juice to take, it is inherent that the “effective” dosage or the dosage as claimed by Applicant is disclosed. In the alternative, it would have been obvious to one of ordinary skill in the art to have altered the dosage to be as

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such claimed by Applicant, because this is a mere “design choice” depending on the severity of the medical condition.

(11) Response to Argument

Starting at page 2 of Applicant’s response, arguments were made regarding the non-enablement rejection made in the previous office action. Those arguments are not deemed persuasive in overcoming the rejection.

It was argued that numerous experiments were performed by Applicant regarding the effect of lime juice as to chest pain. However, no data has been provided by Applicant to show that Applicant’s experiments conform to standard scientific experiments providing at least some proof of sustained effects of presentable treatments for chest pains. Examiner maintains that the effects of lime juice as an active treatment to chest pain, based on the information provided by Applicant is tenuous at the very least. Applicant has shown no proof of the placebo effect as stated in the previous office action, in conjunction to Applicant’s specification describing “beneficial effects” from drinking “a large quantity” or “an effective amount” of lime juice for “chest pain”.

The case law provided in Applicant’s response as to overcoming the 112 rejection regarding “an effective amount” is not persuasive in overcoming the rejection. The case law as stated is distinguished from the facts of this case in such that any “effective amount” referred to in that case is in relation to a known and quantifiable amount of medication. Known medicine in quantifiable amount, based on capsules and pills, even though they are referred to in a medical

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method as “an effective amount” is different from Applicant’s mere recitation of “an effective amount” of lime juice for treatment of “chest pain”.

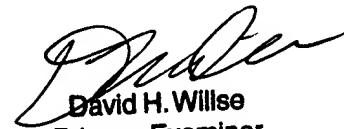
As to Applicant’s arguments regarding the treatment for “chest pain”, starting at the bottom of page 3 of Applicant’s response, these arguments are also not persuasive in overcoming the rejections. It was argued that the prior art does not disclose the treatment for “chest pain”. It is clear that the prior art’s treatment for myocardial infarction or angina fall within the realm of the broad terminology of “chest pain”.

The prior art as applied is replete with information as to using the vitamins commonly found in different juices in their disclosed treatment regimen. The prior art disclosure include using grapefruit juices, orange juices, and lemon juices. Absent a showing of criticality, as indicated in the previous office action, there is considered to be no differences in treatment using lime juice from that of using lemon juice, etc. Applicant’s effort in the written response opposing the rejections made in the previous office action is commendable. However, the rejections are maintained for the above reasons.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



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Primary Examiner

dxn
September 2, 1999

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